

108TH CONGRESS  
1ST SESSION

# H. R. 2218

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## AN ACT

To amend the Federal Food, Drug, and Cosmetic Act to provide for the regulation of all contact lenses as medical devices, and for other purposes.



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To amend the Federal Food, Drug, and Cosmetic Act to provide for the regulation of all contact lenses as medical devices, and for other purposes.

1       *Be it enacted by the Senate and House of Representa-*  
2       *tives of the United States of America in Congress assembled,*

1 **SECTION 1. FINDINGS.**

2 The Congress finds as follows:

3 (1) All contact lenses have significant effects on  
4 the eye and pose serious potential health risks if im-  
5 properly manufactured or used without appropriate  
6 involvement of a qualified eye care professional.

7 (2) Most contact lenses currently marketed in  
8 the United States, including certain plano and deco-  
9 rative contact lenses, have been approved as medical  
10 devices pursuant to premarket approval applications  
11 or cleared pursuant to premarket notifications by  
12 the Food and Drug Administration (“FDA”).

13 (3) FDA has asserted medical device jurisdic-  
14 tion over most corrective and noncorrective contact  
15 lenses as medical devices currently marketed in the  
16 United States, including certain plano and decora-  
17 tive contact lenses, so as to require approval pursu-  
18 ant to premarket approval applications or clearance  
19 pursuant to premarket notifications.

20 (4) All contact lenses can present risks if used  
21 without the supervision of a qualified eye care pro-  
22 fessional. Eye injuries in children and other con-  
23 sumers have been reported for contact lenses that  
24 are regulated by FDA as medical devices primarily  
25 when used without professional involvement, and  
26 noncorrective contact lenses sold without approval or

1 clearance as medical devices have caused eye injuries  
2 in children.

3 **SEC. 2. REGULATION OF CERTAIN ARTICLES AS MEDICAL**  
4 **DEVICES.**

5 Section 520 of the Federal Food, Drug, and Cosmetic  
6 Act (21 U.S.C. 360j) is amended by adding at the end  
7 the following subsection:

8 “Regulation of Contact Lens as Devices

9 “(n)(1) All contact lenses shall be deemed to be de-  
10 vices under section 201(h).

11 “(2) Paragraph 1 shall not be construed as having  
12 any legal effect on any article that is not described in that  
13 paragraph.”.

Passed the House of Representatives November 19,  
2003.

Attest:

*Clerk.*